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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/545,199 | 04/06/2000 | David E. Lowery | 28341/6227.INCP | 9014 |

7590

01/30/2002

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EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 01/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/545,199

Applicant(s)
Lowery et al

Examiner
Portner

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 1, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above, claim(s) 25-30 and 34-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 31-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-51 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7 20) ☐ Other:

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DETAILED ACTION

Claims 1-51 are pending.

Claims 1-24 and 31-33 are under consideration.

Sequence Compliance

1. The instant Application is now in sequence compliance.

Election/Restriction

2. Claims 34-51 of Groups II-VII, and claims 25-30 (*A. pleuropneumoniae*) of Group I are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Groups II-VII, and a non-elected species of Group I, in light of SEQ ID No 3 being a *Pasteurella multocida* nucleotide molecule, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

This application contains claims 34-51 and non-elected species encompassed by Group I, drawn to an invention nonelected with traverse in Paper No. 13. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

3. Applicant's election with traverse of Group I, claims 1-33, SEQ ID NO 3 in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the inventions must be

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independent and distinct and there must be a serious burden on the examiner, and

“Applicants submit that the Examiner has failed to demonstrate that searching the subject matter of asserted Groups I and II would impose a serious burden on the Examiner”.

These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1) independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required. The term “distinct” is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-VII are drawn to distinct inventions which are related as separate products capable of separate functions. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-VII are classified separately necessitating different searches of issued US Patents.

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However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example there are various methods and locations for introduction of a mutation into a gene, as well as polypeptides define a structurally and functionally distinct product from claimed polynucleotides. Additionally, it is submitted that the inventions of Groups I-VII have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

For these reasons the restriction requirement is deemed to be proper and is therefore made Final. Elected claims are claims 1-24, 31-30 in view of the elected species being SEQ ID No 3.

Information Disclosure Statement

4. The information disclosure statement filed February 20, 2001 has been considered as to the merits.

Specification

5. The disclosure is objected to because of the following informalities:

At page 19, lines 25-32 and page 21, Table B, lines 7-17 and 19, the amino acids recited should be separated by commas to indicate that are separate entities and not in association with one another defining a peptide sequence.

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SR At pages 37-38, under the column labeled "LD 50", the numbers 104, 105 and 106 are recited, but in the description of the Table the numbers differ. Clarification of the numbers recited, to define consistent disclosure, is requested.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Please Note: The following rejection is being made of record, in light of the fact that claim 33 depends from claims 1-32 and is directed to a vaccine composition.

8. Claims 1-24 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the introduction of mutations into specific open reading frames, specifically the elected SEQ ID NO3, for the production of an immunogenic recombinant bacteria, does not reasonably provide enablement for formulation of vaccines for any gram negative bacteria, with any mutation in SEQ ID NO 3 or a species homolog of SEQ ID No 3 for the induction of a protective immune response. The specification does

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not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification fails to teach how to formulate and use the claimed vaccines utilizing any gram negative bacteria that comprises a mutation in SEQ ID No 3 or a species homolog of SEQ ID NO 3, which upon administration to an immunocompetent animal would prevent infection and disease or treat pre-existing disease.

The term "vaccine" encompasses the ability of the specific gene product to induce protective immunity against infection or disease induction. The specification suggests that gram negative bacteria with a mutation in SEQ ID No 3, or in a species homolog of SEQ ID NO could be used in the prevention and treatment of infections.

The specification does not provide substantive evidence that the claimed vaccines are capable of inducing protective immunity utilizing any mutant strain of gram negative bacteria that evidences any level of decreased activity for the gene products of SEQ ID NO 3 or for gene products from species homologs of SEQ ID NO 3. The claimed mutant gram negative bacteria are not required to be attenuated, but only evidence some level of decreased activity of a gene product, and some level of decreased level of gene expression. A virulent strain of gram negative bacteria with mutations in SEQ ID NO 3 that do not attenuate the bacterium would result in induction of infection, not production upon administration. This demonstration is required for the skilled artisan to be able to use the claimed vaccines for their intended purpose of preventing infections caused by gram negative bacteria. Without this demonstration, the skilled artisan would not be able

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to reasonably predict the outcome of the administration of the claimed vaccines, i.e. would not be able to accurately predict if protective immunity has been induced.

The ability to reasonably predict the capacity of a bacterial immunogen to induce protective immunity from in vitro antibody reactivity studies or in vivo induced antibody titers is problematic. The prior art provides evidence of unpredictability for bacterial antigen containing compositions to induce a protective immune response against challenge. Zeman et al (1993) cautions against the utilization of "modified live vaccines" because they are "intrinsically more hazardous than inactivated products" and teaches that some of the vaccine compositions resulted in systemic infection, and not protection (see title, page 559, col. 1, paragraph 3). Confer et al (1984) teach that while antibody titers could be determined, the compositions "do not induce protection against transthoracic challenge exposure to *P.haemolytica* (see page 342, col. 1, paragraph 3, last sentence). Chandrasekaran et al (1991) teaches that a composition that contained both *P.multocida* and *P. haemolytica* strains did not protect against infection and did not show any significant reduction of lung lesions (abstract, page 437). Jones et al (1986) teaches that a composition administered for the induction of a protective immune response was not protective against *P.haemolytica* A2 (abstract, page 193, paragraph 2). Cameron et al (1986) teaches that oil emulsion compositions of *P.haemolytica* may in fact depress the immune response of a host and teaches that *P.haemolytica*, type 2 cells are notoriously poor antigens (see page 6, col. 1, paragraphs 1-3)

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Unfortunately, the art is replete with instances where even well characterized antigens that induce an in vitro antibody response fail to elicit in vivo protective immunity. Accordingly, the art indicates that it would require undue experimentation to formulate and use a successful vaccine without the prior demonstration of vaccine efficacy.

Further, the specification fails to provide an adequate written description of all the species of SEQ ID 3 that evidence attenuating mutations, and species homologs of SEQ ID NO 3 that would result in a recombinant gram negative bacteria that would serve to induce a protective immune response. The skilled artisan would be required to de novo locate, identify and characterize the claimed species homologs of SEQ ID NO 3 from all gram negative bacteria that are not known and to determine wherein a mutation could be introduced that would result in an attenuated gram negative bacteria that will induce a protective immune response.

9. Claims 1-33 are rejected under 35 U.S.C. 112, first paragraph (scope), as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While the instant specification discloses SEQ ID No 3 obtained from *Pasteurella* *moltocida*, that is taught to have a possible, potential, gene function of *atpG* (see Table 1, page 37, instant specification, bottom of page) and SEQ ID No 132, obtained from *Actinobacillus* *pleuropneumoniae*, which is taught to encode *atpG* activity, no other specific genes (open reading

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frames) that encode species homologs of the identified nucleic acid sequences meet the written description requirement by providing a representative number of species of the claimed genus recombinant bacteria with mutations in species homologs of nucleic acid sequences of SEQ Id No 3 and are mutated to evidence reduced gene product activity, and/or reduced expression of the encoded gene product.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

With the exception of SEQ ID NO: 3 and 132, the skilled artisan cannot envision the detailed structure of the encompassed polynucleotides that encode the functional gene product elected and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation, for all of the members of the Family of bacteria Pasteurellaceae and the genera grouping of all gram negative bacteria. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating the nucleic acid molecule. The nucleic acid that encodes the gene

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product itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, In *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of screening for nucleic acid molecules that would hybridize under low stringency is made in the specification. The instant specification lacks sufficient support for the generic claims as provided by the Interim Written Description Guild lines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

10. Claims 1-24, 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1-24, 31-33 recite non-elected inventions and therefore do not distinctly claim

Applicant's invention.

Claims 1-24, 31-33 recite the phrase "a gene". What is the gene? What type of activity does the gene encode for?

Claims 1-24, 31-33 are directed to a gram negative bacteria with a mutation in a gene which results in "decreased activity of a gene product". Claims 1-24, 31-33 recite the elected invention of SEQ ID No 3: nucleotides 1-363 (partial sequence) of SEQ ID NO 3 evidence homology with atpA, nucleotides 364-1233 evidence homology with atpG and nucleotides 1234-1972 evidence homology with atpD; each corresponding to a subunit of F1- ATP synthase. When the claims are read in light of the elected sequence, the claims do not distinctly claim Applicant's invention because SEQ ID NO 3 includes two full open reading frames and a partial 3' end segment of a third open reading frame. SEQ ID NO 3 comprises a mutation in the open reading frame that shares homology with atpA (nucleotides from the 3' end of the gene, nucleotides 1-

363). Is the invention SEQ ID NO 3 which already comprises a mutation of atpA? If this is the case, how can the whole gene product for atpA be expressed with any type of activity, in light of only a portion of the sequence being present in SEQ ID NO 3 and would not have any activity at all. What is the gene product that must have decreased activity in light of the fact that SEQ ID NO 3 encodes for three different gene products, only one of which has been mutated in SEQ ID NO. 3? What kind of gene product would be expressed for nucleotides 1-363, since the full subunit sequence is not included?

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Claims ~~2~~, 8, 14, 20 recite the phrase "decreased expression of a gene product". Which of the three gene products does the decreased expression refer in light of the elected invention is SEQ ID NO 3 which encodes for three gene products? Where is the mutation that controls expression of the encoded gene product? Is the mutation in the open reading frame or in the nucleotide sequence that controls transcription of the open reading frame?

Claims ~~2~~ or 8, 14, 20 depend from claims 1 or 7, respectively, and define the mutation to result in "decreased expression of a gene". The independent claims define the bacteria to comprise a mutation that results in "decreased activity of a gene product". While it is possible to have two mutations in a bacteria, how a mutation that results in decreased expression effects that activity of the protein (gene product) is distinctly claimed. The bacteria of the independent claim is defined to have a single mutation, and claims 2, or 8, 14, 20 recite a clarification "wherein" statement that defines the presence of a second mutation that is not defined in the independent claim. A mutation that results in decreased expression of a gene would not necessarily result in reduced activity of the gene product, but could result in a gene product that is fully active, but just produced at a lower level. The dependent claims should be amended to recite the phrase "further comprising" to define the presence of two mutations.

Claims 3, 9, 15, 21 recite the phrase "an inactive gene product". Which gene product is inactive, in light of the fact that SEQ ID No 3 encodes for three gene products? The first 343 nucleotides already encode for an inactive gene product, is this what is intended?

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Claims 4, 10, 16, 22 are dependent claims that recites the phrase "deletion of all or part of said gene" while the independent claims require the expression of the gene product but with decreased activity. With the complete deletion of the gene, the gene product would not be expressed as required. With the partial deletion of a gene, what type of gene product would be expressed? Which of the three gene products encompassed by SEQ ID NO 3 is deleted to meet the claim limitations recited? Clarification is requested.

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Claims 5, 11, 17, 23 are dependent claims and define the mutation to be a deletion of a gene. Which gene is deleted from SEQ ID No 3? What activity would the gene product have if the gene is deleted by at least 10% to complete deletion of the nucleotide sequence?

ok
Claims 6, 12, 18, and 24 are dependent claims and define the mutation to be "an insertion in the gene". The insertion may result in decreased expression of the gene product or the expression of an inactive gene product. As discussed above for claim 2, how decreased expression of a gene results in a change in product activity (independent claim limitation) is not clearly pointed out. Where is the insertion in SEQ ID NO 3 and what activity is being decreased based upon the insertion, in light of SEQ ID NO 3 encoding three different gene products? Would the insertion into SEQ ID No 3 restore the complete reading frame for aptA? Clarification is requested.

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Claim 13 recites non-elected species of invention through the election of SEQ ID No 3 which is a *Pasteurella multocida* nucleic acid molecule (see locus Accession Number AF237922

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which defines nucleotides 364-1233 as encoding ATP-synthase subunit, gamma). Amendment of the claim to delete the non-elected inventions would distinctly claim Applicant's invention.

Claims 31-33 depend from claims non-elected and withdrawn from consideration.

Claim Rejections - 35 U.S.C. § 102


11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Please Note: Rejections over claims 31-32 are being made of record in light of the claims being read as compositions of recombinant mutant gram negative bacteria in association with any acceptable carrier.

12. Claims 1-5, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakamoto et al (1993).

 (Generic claims) The claimed invention is directed to a gram negative bacteria with a mutation in a gene that is a species homolog of SEQ ID NO 3, (encodes ATP-synthase, gamma subunit).

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(Claims 1,2,4,5, 31-32) Nakamoto et al disclose a gamma subunit deficient strain of E.coli, a gram negative bacteria (see page 868, col. 1, Bacterial strain and Growth conditions section).

(Claims 1 and 2) Nakamoto et al disclose a E.coli, strains with site-directed mutations at the carboxyl-terminal of the gamma subunit, in the conserved amino acids, which resulted in an ATPase with lower activity (see page 867, col. 2, paragraph 2, last two sentences).

(Claims 1 and 3) Nakamoto et al disclose mutant strains of gram negative bacteria that evidence mutations that prevent the assembly of mature ATP synthase, the encoded gene product. Without assembly of the ATP-synthase, the gene product would be inactive (see page 867, col. 2, paragraph 2).

Inherently the reference anticipates the now claimed invention.

13. Claims 1-2, 6, 7-8, 12, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Gwinn et al (Dec. 1997).

The claimed invention is directed to a mutant gram negative bacteria, a member of the Family of Pasteurellaceae, which is a species homolog of SEQ ID NO 3, wherein the mutant evidences reduced activity of a gene product, decreased expression of a gene product and is the result of an insertion into a species homolog of SEQ ID NO 3.

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Gwinn et al disclose a mutant gram negative bacteria, a member of the Family of Pasteurellaceae, Haemophilus influenzae which evidences reduced activity of a gene product (abstract, significant reduction of expression of competence-regulatory gene), decreased expression of a gene product (evident in reduced growth, see page 7317, col. 2, paragraph 5) and is the result of an insertion into the gene which is a species homolog of SEQ ID NO 3 (see title, abstract, Table 1: IDR30, MGH11, MGH30, MGH31, MGH40; page 7317, col. 2, paragraph 5 and page 7318 both columns and discussion section starting at page 7319).

Inherently the reference anticipates the now claimed invention which recites a mutant strain of bacteria that comprises a mutant species homolog of SEQ ID NO 3.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
15. Bacmeister et al (1997) is cited to show Actinobacillus pleuropneumoniae's ATP synthase gene partial sequence (EMBL record).
16. Bergeron et al (US Pat. 5,994,066) is cited to show Haemophilus influenza ATP synthase, atpD nucleic acid sequence alignment with SEQ ID NO 3, nucleotides 1251-1972, complete open reading frame (ATG start and TAA stop codons noted), see col. 29, Table 8, SEQ ID NO 187.

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17. Borghese, R et al (Jan. 1998) is cited to show a bacterial ATP synthase operon that comprises the gamma subunit.
18. Chen et al (1998) is cited to show a mutation in the C-subunit of ATP synthase results in suppression of rhoO lethality.
19. Humbert et al (1989) is cited to show a defective ATP synthase results in antibiotic resistance.
20. Kaim et al (1995) is cited to show an ATP synthase mutant gram negative bacteria that comprises the atpG (gamma) subunit, which evidenced a change in biological activity.
21. Kullen et al (6,242,194) is cited to show recombinant bacteria that contain mutations in the atp operon for increase expression of the associated open reading frame gene products.
22. Tomita et al (US Pat. 6,214,591) is cited to show mutant gram positive bacteria that are deficient in ATPase activity.
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp

January 25, 2002



**MARK NAVARRO
PRIMARY EXAMINER**